REMARKS

Reconsideration of the present application is respectfully requested in view of the above Amendments and the following remarks. Claims 1-64 are currently pending. Applicants affirm election of Group I, claims 1-19 and 41-60, as indicated in the Response to Restriction Requirement submitted to the U.S. Patent and Trademark Office (PTO) on November 18, 2005.

Applicants have amended claims 1, 8-11, 19, 44, 46, 50-52, and 59 to point out with more particularity and to claim distinctly certain embodiments of Applicants' invention. Applicants hereby cancel claims 4-7, 15-18, 20-43, 47-49, 56-58, and 61-64. Accordingly claims 1-3, 8-14, 19, 44-46, 50-55, and 59-60 are currently under examination. The above Amendments are not to be construed as acquiescence to the stated grounds for objection or rejection and are made without prejudice to prosecution of any subject matter modified or removed by this amendment in a related divisional, continuation, or continuation-in-part application. No new subject matter has been added to the application. Support for the amended claims may be found throughout the specification, for example, at page 8, paragraph [0045]; page 9, paragraph [0053]; page 10, paragraph [0055]; page 11-12, paragraph [0061]; pages 18-19, paragraph [0085]; page 24, paragraph [00101]; and page 24, paragraph [00104].

Applicants note that the Office Action Summary indicates that claims 1-19 and 41-60 stand rejected. However, the Office Action does not indicate any basis for objection or rejection of claims 44 and 45. Applicants request clarification of the status of claims 44 and 45.

Objection to the Abstract

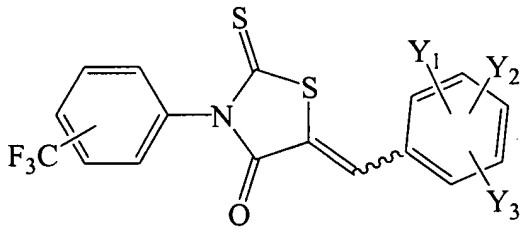
The Examiner objects to the Abstract, asserting that the Abstract "is not directed to the subject matter currently under examination." The Examiner requires correction of the Abstract.

Applicants respectfully submit that the Abstract conveys the nature and gist of Applicants' invention. Applicants have hereby amended the Abstract to delete description of embodiments that are not currently under examination. The Abstract therefore meets the requirements under 37 C.F.R. § 1.72 and MPEP § 608.01(b), and Applicants request that this objection be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph (Enablement)

The Examiner rejects claims 1-19 and 41-43 under 35 U.S.C. § 112, first paragraph, alleging that the claimed subject matter is not enabled by the specification. Specifically, the Examiner asserts that the scope of the claims is not commensurate with the subject matter enabled by the disclosure.

Applicants traverse this rejection and submit that the specification enables a person skilled in the art to make and use, without undue experimentation, the presently claimed compositions and methods. Solely to expedite prosecution of specific embodiments, Applicants have cancelled certain subject matter and amended the claims without acquiescence or prejudice. Accordingly, in one embodiment, the claimed subject matter (see claim 46) relates to a pharmaceutical composition comprising a compound of formula (Ic), as shown below,



(Ic)

wherein Y_1, Y_2, and Y_3 are independently chosen from hydrogen, an aliphatic group, a halo group, a nitro group, an azo group, a hydroxyl group, and a mercapto group. In another embodiment (see claim 1), the claimed subject matter relates to a method of treating a subject having a cystic fibrosis transmembrane conductance regulator (CFTR) protein-mediated condition or symptom that is treatable by inhibiting CFTR-mediated ion transport. The method comprises administering to the subject a therapeutically effective amount of a compound of formula (Ic) wherein Y_1, Y_2, and Y_3 are defined as described above.

The present application provides abundant guidance to a person skilled in the art to make and use the claimed compositions and methods, readily and without undue experimentation. As described in the present specification and recited in the instant claims, a thiazolidinone compound of formula (Ic) is capable of inhibiting aberrant CFTR-mediated ion transport (*see, e.g.*, page 24, paragraph [00104]), which may be used for treating conditions and symptoms related to such aberrant ion transport. The specification also teaches that conditions

and symptoms that are treatable by inhibiting aberrant CFTR-mediated ion transport include, for example, increased intestinal secretion of fluids, intestinal inflammatory disorders, and diarrhea, including secretory diarrhea (*see, e.g.,* page 23-24, paragraphs [00105-00106]).

Furthermore, the specification teaches exemplary methods for determining the capability of a thiazolidinone compound to inhibit CFTR-mediated ion transport (*see, e.g.,* pages 34-35, paragraphs [00146] and [00147]), and discloses in working examples that numerous thiazolidinone compounds of formula (Ic) inhibit CFTR-mediated ion transport (*see, e.g.,* pages 41-42, paragraphs [00167] and [00168]; *see also, e.g.,* pages 42-50, Examples 2-7). Contrary to the assertion in the Action that "[n]o guidance is provided to select another of the plethora of compounds encompassed in the depiction of instant formula (I)" (*see* Action, page 5, 2nd paragraph), the screening methods described in Example 1 (page 40, paragraph [00165] through page 42, paragraph [00168]) were used to screen more than 50,000 compounds and successfully identified several thiazolidinone compounds that inhibited CFTR-mediated ion transport (*see, e.g., In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) ("Enablement is not precluded by the necessity for some experimentation such as routine screening.")). Additional methods, incorporating $CFTR_{inh}$-172 as an exemplary compound, are described in working examples for characterizing and determining the capability of thiazolidinone compounds to inhibit CFTR-mediated ion transport (*see, e.g.,* pages 42-50, Examples 2-7).

Accordingly, the scope of the present claims is commensurate with the subject matter enabled by the disclosure, and the present application meets the enablement requirements under 35 U.S.C. § 112, first paragraph. Applicants therefore request withdrawal of this rejection.

Rejection Under 35 U.S.C. § 112, First Paragraph (Written Description)

The Examiner rejects claims 1-19 and 46-60 under 35 U.S.C. § 112, first paragraph, asserting that the claims are directed to subject matter that is not adequately described in the specification.

Applicants respectfully traverse this rejection and submit that, as disclosed in the specification and recited in the instant claims, the application reasonably conveys to a person skilled in the art that Applicants possessed the claimed invention at the time of filing. While

Applicants strongly disagree with the Examiner's assertion that the metes and bounds of certain phrases and terms cannot be precisely determined, such phrases and terms have been removed, thus rendering this rejection moot.

As noted above, the present claims are directed, in pertinent part, to compositions comprising a compound of formula (Ic) wherein Y_1, Y_2, and Y_3 are independently chosen from hydrogen, an aliphatic group, a halo group, a nitro group, an azo group, a hydroxyl group, and a mercapto group; or a pharmaceutically acceptable salt thereof, as an individual stereoisomer or a mixture thereof, and methods for using such a compound. A compound of formula (Ic) is described in the application, for example, at pages 18-19, paragraph [0085], and methods for making these compounds are provided at pages 27-31. Relevant and identifying characteristics of representative species of a compound of formula (Ic) are further described in working examples at pages 40-42, paragraphs [00165]-[00168] (Example 1). The specification also describes that each of Y_1, Y_2, and Y_3 may independently be an organic group, which includes an aliphatic group that is defined at pages 11-12, paragraph [0061]. A composition comprising such a compound also comprises a pharmaceutically acceptable excipient such as a pharmaceutically acceptable vehicle, carrier, and/or diluent (*see generally* page 20-24, paragraphs [0087] – [00101]).

Applicants therefore submit that the claimed subject matter is supported by the disclosure of the application as required under 35 U.S.C. § 112, first paragraph, and request that this rejection be withdrawn.

REJECTION UNDER 35 U.S.C. § 102

The Examiner rejects claims 46-60 under 35 U.S.C. § 102(b), alleging that the subject matter of these claims is anticipated by Roman et al. (*Framatsevtichnii Zhurnal* (Kiev) 3:56-59 (2002)). The Examiner alleges that Roman et al. teach a compound of formula I, 3-aryl-5-arylidene-2-thioxothiazolidine-4-ones, and teach a preparation of this compound for use in a therapeutic application.

Applicants respectfully traverse this rejection. The compounds described in Roman et al. fall outside the compounds of formula (Ic) as recited in claim 46 and claims

dependent thereon; therefore, Roman et al. fail to destroy the novelty of the present claims. Furthermore, this reference does not suggest a composition comprising a 3-aryl-5-arylmethylene-2-thioxo-4-thiazolidinone compound that has the structure of formula (Ic). More specifically, the cited document fails to teach or suggest that at the 3-aryl position is a phenyl substituted with a trifluoromethyl group. Roman et al. instead describe thiazolidinone compounds that at the 3-aryl position have a phenyl substituted with only a chlorine or a bromine (*see* Roman et al., page 57; the entire article as published and an English translation of the text are enclosed herewith for the Examiner's convenience). Moreover, the cited art fails to provide any teaching, suggestion, or motivation to modify the teachings therein such that a person having ordinary skill in the art would reasonably expect to obtain the presently claimed compositions.

Therefore, the presently claimed subject matter is patentable over Roman et al., and Applicants respectfully request that this rejection be withdrawn.

Applicants submit that all claims in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

Mae Joanne Rosok

Mae Joanne Rosok
Registration No. 48,903

Enclosures:

Third Supplemental Information Disclosure Statement
Roman et al., (*Framatsevtichnii Zhurnal* (Kiev) 3:56-59 (2002) (untranslated)
Roman et al., (*Framatsevtichnii Zhurnal* (Kiev) 3:56-59 (2002) (translated text)

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031